#17 Response 8/1/03

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

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Alan H. Norman
Registration No. 32,285

Application of:	Streibig	**Group No.:**	2873
Serial No.:	09/821,620	**Atty. Docket No.:**	54052-7414
Filed:	March 29, 2001		
For:	Colored Contact Lens and Method of Making Same	**Examiner:**	Jordan M Schwartz

Assistant Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

RESPONSE TO OFFICE ACTION

This document is responsive to the Office Action dated December 9, 2002.

A. Claims 22-27 Ar N t Mad Obvious By N fe U.S. Patent No. 4,701,038.

Independent claim 22 is directed to a colored contact lens having, among other things, a multi-color composite pattern on the iris region. The composite pattern comprises a plurality of distinct elements.

The Neefe patent discloses a cosmetic contact lens, which is formed by cutting a disc from a cylinder. The cylinder has a transparent center 3 surrounded by a transparent colored polymer 1. Light reflecting particles 5 are imbedded in the colored polymer. The light reflecting particles 5 "have no color of their own." Column 3, lines 34-35. The Neefe patent does not disclose a multi-color composite pattern on a contact lens. Rather the colored polymer is of a single color. The Neefe patent also does not disclose or suggest any multi-color pattern or any color pattern.

The Examiner takes the position that Neefe's disclosure of "pigments" being mixed together would somehow make obvious of to a person of ordinary skill in the art a multi-color pattern. However, mixing pigments together in the manner disclosed in the Neefe patent would produce a single unitary color. The particular color produced would depend upon the types and ratios of the pigments selected. Thus, the Neefe patent does not disclose or suggest a multi-color pattern as required by Applicant's claim 22. The Examiner also takes the position that the Neefe reflecting particles would constitute claim 22's distinct elements. However, the Neefe patent discloses that the reflecting particles have no color of their own. Column 3 lines 34-35. Thus, Neefe's reflecting particles cannot constitute distinct elements of a multi-color composite pattern as required by Applicant's claim 22. The Examiner also suggests that it would somehow be obvious to a person of ordinary skill in the art to have made the iris portion of the

Neefe contact lens multi-colored. Howev r, the Examiner provides no rational as to how a contact lens made by the Neefe proc ss could be modified to form a contact lens having a multi-colored composite pattern. The Neefe patent itself provides no disclosure, suggestion, or teaching for a multi-colored composite pattern. Additionally, the Examiner has cited no prior art reference which would suggest a change of the Neefe patent. To set forth a *prima facia* case of obviousness, the Examiner must provide evidence to make changes to the patent. For example, to set forth a *prima facia* case of obviousness based on the Neefe patent combined with another patent, the Examiner must show some evidence in the prior art for making the combination. Because the Examiner has provided no evidence that one of ordinary skill in the art would have been led to modify the Neefe patent to arrive at Applicant's claimed invention, the Examiner has not met his burden of establishing that the Neefe patent makes obvious Applicant's claim 22.

Claims 23-27 depend from claim 22. Accordingly, claims 23-27 are not made obvious by the Neefe patent for the same reasons that claim 22 is not made obvious. Thus, the rejection of claims 22-27 based on the Neefe patent should be withdrawn.

B. The Examiner Should Withdraw All Claim Rejections Based in Whole or in Part On Ocampo Application Publication 2002/0039172

The Examiner has not established that Ocampo Patent Application Publication ("the Ocampo Publication") is prior art against the present application. The present application was filed March 29, 2001. The Ocampo Publication is based on an application filed June 12, 2001, after th filing date of the present application. The

Ocampo application purports to claim priority to provisional application 60/211,236 filed June 12, 2000. However, pursuant to 35 USC 119(d), a patent application is not entitled to the benefit of the filing date of a provisional application unless the provisional application satisfies the requirements of the first paragraph of 35 USC 112. In the present case, the Ocampo Publication cannot be considered prior art against the present application unless the Examiner can establish that the Ocampo provisional application satisfies the requirements of 35 USC 112. At a minimum, the Examiner must supply a copy of the provisional application to Applicant. In a telephone conference with the Examiner, Applicant's counsel asked the Examiner to supply him with a copy of the provisional application. The Examiner informed Applicant's counsel that although he wanted to send a copy of the provisional application to Applicant's counsel, he was prohibited from doing so. Applicant's counsel appreciates the Examiner's effort in trying to supply him with a copy of the provisional application. On February 19, 2003, Applicant's counsel attempted to order a certified of the Ocampo provisional application from the Patent and Trademark Office. However, Applicant's counsel has been unable to obtain any such copy. Because the Examiner has not provided a copy of the Ocampo provisional application to Applicant (albeit for reasons perhaps beyond the Examiners control), the Examiner has not met his burden of establishing that the Ocampo Publication is entitled to the benefit of the filing date of the provisional application. Thus, the Examiner has not met his burden of establishing that the Ocampo Publication constitutes prior art. Because the Ocampo Publication does not constitute prior art, the rejections of any claims based on the Ocampo Publication should be withdrawn. In particular, the Examiner should withdraw: (1) th rej ction of

claims 22-27 and 41-42 based on the Ocampo Publication; (2) the rej ction of claims 28, 29 and 39 based on the combination of the Ocampo Publication and Atkins U.S. Patent 6,132,043; and (3) the rejection of claims 30-38 and 40 based on a combination of the Ocampo Publication and Tucker Patent Application Publication 2001/0050753 (the "Tucker Publication").

C. The Examiner Should Withdraw The Rejections Of Claims 43 And 44 Based On The Atkins Patent And The Tucker Publication.

The Tucker Publication is based on an application filed June 12, 2001, a date after the filing date of the present application. The Tucker Publication purports to claim priority based on Provisional Application 60/213,217, filed June 20, 2000, and Provisional Application 60/211,043 filed June 12, 2000. As stated above, the Examiner bears the burden of proving that the Tucker provisional applications satisfy the requirements of 35 USC 112, first paragraph. The Examiner has not provided Applicant with copies of the Tucker provisional applications and has not otherwise provided any proof that the Tucker Publication is entitled to a priority date earlier than Applicant's present application. Because the Examiner has not established that the Tucker Publication constitutes prior art against Applicant's present application, the Examiner should withdraw the rejections of claims 43 and 44 based on the Tucker Publication.

D. Conclusion

For the reasons disclosed above, Applicant requests that the Examiner withdraw all of the claim rejections. Applicant further requests that the Examiner issue a notice of allowance, allowing all pending claims.

Respectfully submitted,

THOMPSON COBURN LLP
By:

Alan H. Norman
Reg. No. 32,285
One US Bank Plaza
St. Louis, Missouri 63101
(314) 552-6284

THOMPSON COBURN

Thompson Coburn LLP
Attorneys at Law

One US Bank Plaza
St. Louis, Missouri 63101-1693
314-552-6000
FAX 314-552-7000
www.thompsoncoburn.com

Facsimile

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A/PROV.

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(c).

Docket Number	7651-1494	Type a plus sign (+) inside this box	+

INVENTOR(S)/APPLICANT(S)

Last Name	First Name	Middle Initial	Residence (City And Either State Or Foreign Country
Ocampo	Gerardo	J.	6918 olympic Dr. Bridgeview IL 60455
Quinn	Michael	H.	4302 Waldon Lane Valparaiso, IN 46383

TITLE OF INVENTION (280 characters max)

~~COMPUTER GENERATED COLOR CONTACT LENS~~

COLORED CONTACT LENS HAVING A MORE NATURAL APPEARANCE AND METHOD OF MAKING SAME

CORRESPONDENCE ADDRESS

Linda D. Kennedy
BRINKS HOFER GILSON & LIONE
P.O. Box 10395
Chicago

STATE	IL	ZIP CODE	60610	COUNTRY	

ENCLOSED APPLICATION PARTS (check all that apply)

☒ Specification	Number of Pages	28+cover	☐ Small Entity Statement
☒ Drawing(s)	Number of Sheets	6	☐ Other (specify)

METHOD OF PAYMENT (check one)

☒ A check or money order is enclosed to cover the Provisional filing fees. ☐ The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number **23-1925**	PROVISIONAL FILING FEE AMOUNT(S)	150.00

The invention was made by an agency of the United States Government or under a contract with an Agency of the United States Government.

☒ No.
☐ Yes, the name of the U.S. government agency and the Government contract number are:_____.

Respectfully submitted,

SIGNATURE:
TYPED OR PRINTED NAME: Linda D. Kennedy

Date: June 12, 2000
Registration No. 44,183 (if appropriate)

☐ Additional inventors are being named on separately numbered sheets attached hereto.

PROVISIONAL APPLICATION FILING ONLY

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Case No. 7651/1494

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PROVISIONAL APPLICATION FOR UNITED STATES LETTERS PATENT

INVENTORS: GERARDO J. OCAMPO
6918 Olympic Dr.
Bridgeview, IL 60455
MICHAEL H. QUINN
4302 Waldon Lane
Valparaiso, IN 46383

TITLE: COLORED CONTACT LENS HAVING A MORE NATURAL APPEARANCE AND METHOD OF MAKING SAME

ATTORNEYS: LINDA D. KENNEDY
Reg. No. 44,183
STEVEN P. SHURTZ
Reg. No. 31,424
BRINKS HOFER GILSON & LIONE,
INTELLECTUAL PROPERTY ATTORNEYS
NBC TOWER - SUITE 3600
455 NORTH CITYFRONT PLAZA
CHICAGO, ILLINOIS 60611

COLORED CONTACT LENS HAVING A MORE NATURAL APPEARANCE AND METHOD OF MAKING SAME

TECHNICAL FIELD

The present invention relates to making colored contact lens designs, especially lens designs that are created by separating out the different color designs from an image of a human iris and then printing each of the different color designs onto a contact lens to obtain a colored contact lens that replicates the complex appearance of the iris.

BACKGROUND OF THE INVENTION

The initial attempts to modify or enhance the color of one's iris used contact lenses with a solidly colored area that covered the iris portion of the eye. One example of contact lenses of this type disclosed in U.S. Patent No. 4,468,229 (Su) was a contact lens colored over at least a portion of its surface, comprising a copolymeric hydrogel material to which at least one reactive dystuff of a particular chemical formula is reacted. It is difficult to achieve multiple complex patterns with this technology.

Colored contact lenses were developed, such as those discussed in Wichterle, U.S. Pat. No. 3,679,504, in which an opaque lens having an iris of multiple colors was artistically drawn or photographically reproduced onto the iris portion of the lens. However, these lenses also failed to look natural, and as such never achieved commercial success. Other attempts to produce an opaque lens with a natural appearance are disclosed in U.S. Pat. Nos. 3,536,386 (Spivak); 3,712,718 (LeGrand); 4,460,523 (Neefe); 4,719,657 (Bawa); 4,744,647 (Meshel et al.); 4,634,449 (Jenkins); and in European Patent Publication No. 0 309 154 (Allergan) and U.K. Patent Application No. 2 202 540 A (IGEL).

The first commercially successful opaque colored contact lens was manufactured based on the invention by Knapp as disclosed in U.S. Pat. No. 4,582,402. Knapp disclosed a contact lens having, in its preferred embodiment, colored, opaque dots, not a solidly colored iris portion. The Knapp lens provides

a natural appearance with a lens that is simple and inexpensive to produce, using a simple one-color printed dot pattern. Although the intermittent pattern of dots does not fully cover the iris, it provides a sufficient d nsity of dots that it creates a masking effect. The person wearing the lens has the appearance of a nearly continuous color when viewed by an ordinary observer. Knapp also discloses that the printing step may be repeated one or more times using different patterns in different colors, since upon close examination the iris is found to contain more than one color. The printed pattern need not be absolutely uniform, allowing for enhancement of the fine structure of the iris. The one-color Knapp lenses currently achieving commercial success have their dots arranged in an irregular pattern to enhance the structure of the iris.

Various efforts have been made to improve on the Knapp lens. U.S. Patent No. 5,414,477, issued to Jahnke, discloses the application of intermittent ink patterns in two or three portions of distinct shades of colorant to provide a more natural appearance. The Jahnke disclosure describes a jagged border used to separate the distinctly colored portions, thereby enhancing the natural appearance of the colored lens. The Jahnke disclosure also describes three distinct colored portions and the use of multiple jagged borders to provide the necessary separation.

Other attempts to create a more natural appearing lens include U.S. Patent No. 5,120,121 to Rawlings, which discloses a cluster of interconnecting lines radiating from the periphery of the pupil portion to the periphery of the iris portion. Further, European Patent No. 0 472 496 A2 shows a contact lens having a pattern of lines that attempts to replicate the lines found in the iris.

Despite these efforts, the contact lens industry continues to seek a low-cost, colored lens that can enhance or modify the color of the iris while providing its inherent depth and texture. This objective has been more closely achieved by providing colored contact lenses that allow some of the natural iris color and pattern to show through the colored lens.

SUMMARY OF THE INVENTION

The present invention provides a colored contact lens. Preferably, the contact lens is produced by selecting an image of an eye of choice, breaking that image down into its component colors and patterns, processing the component colors and patterns, and reproducing those colors and patterns onto a contact lens, either directly or indirectly.

Initially, an image of a human eye may be recorded either by photographic means or some other reproduction means. Alternatively, an image of a human eye can be created by any graphical arts methods. Optionally, the recorded image can be enhanced at this time to achieve a particular cosmetic effect.

Next, the recorded image is processed to separate the image into its multiple component colors and their associated patterns. Optionally, these colors and patterns can be enhanced to achieve a particular cosmetic effect. The separation process can be done using a computer and commercially available software. These component colors and patterns are then used to manufacture multiple plates containing opaque or near-opaque portions, which can be used in the color lens manufacturing process. The colored lens is then manufactured by printing multiple layers of opaque or near-opaque portions in a particular order onto a contact lens using any known printing technique.

The recorded image, or some or all of the individual component colors, can be altered or modified in many different ways if desired, to produce a pattern suitable for changing the appearance of an eye. Such methods of alteration include removing some of the darker shades from the recorded image or the individual component colors; converting the component colors and their associated patterns into elements such as dots or islands of color; matching the component colors with available pigments and associated inks (such pigments and inks may be approved by the Food and Drug Administration, thereby increasing the chance of governmental approval); enhancing the recorded image or the component colors and patterns with additional colors and patterns, radial lines, contrast zones and the like; using certain mathematical algorithms such as two-dimensional Fourier transforms; and other manipulations of the patterns

using software such as Adobe PhotoShop. Such modifications can be performed on the recorded image prior to processing the recorded image into separate component colors and patterns. The modifications may also be applied to the individual component colors after such processing.

The improvement in appearance over one-color lenses, two and three color lenses, and the other disclosures in which an attempt is made to replicate the human eye, is quite distinctive. Like certain previous color lenses, the lenses manufactured in accordance with this invention allow a fundamental change in the apparent color and color pattern of the wearer's iris. For example, it is not difficult to change the apparent iris color from dark brown to light blue or green, etc. Although the preferred embodiment of the invention is a four-color portion or layer lens, fewer or more than four layers are also contemplated. The number of layers is merely that desired by the operator who commands the software used to separate out the requested number of colors and patterns from the recorded image of the human eye. Generally, the more colors and patterns separated out and printed onto the colored contact lens, the closer the lens approximates the human eye and the desired cosmetic appearance effect on the eye.

One objective of a preferred embodiment of the invention is to provide a colored contact lens with a pupil section, an iris section surrounding the pupil section, and a colored pattern over the iris section. The colored pattern is preferably generated by recording a cosmetically appealing human eye or a photograph of such an eye, and then separating the recorded image into multiple component colors in their associated patterns. The multiple color separations are then used to create the different portions used in the printing process to manufacture the colored lens. A separate plate or cliché is created for each of the different portions consisting of the particular color separated out from the recorded image. These plates are then used to print each of the different colors or layers onto the contact lens or onto a film in a mold where a contact lens is formed, such that the film becomes part of the final contact lens. The final lens contains all of the layers and colors and closely replicates the image of the human eye that was originally recorded. The colored contact lens is capable of

changing the apparent color and color pattern of the iris of a person wearing the lens, while imparting a very natural appearance.

The component colors and their associated patterns can be reproduced on contact lenses many ways. Rawlings' U.S. Patent No. 5,116,112, incorporated herein by reference, discloses a printing method involving printing ink onto a layer or a film in a casting mold, forming a contact lens, and removing the contact lens so that the layer or film comprising the ink become part of the surface of the contact lens. Knapps' U.S. Patent Nos. 4,704,007 and 4,582,402, incorporated herein by reference, disclose a method of pad printing contemplated for use with this invention. Other methods of reproducing an image on a contact lens such as laser printing and ink jet print are also contemplated.

Another objective of a preferred embodiment of the invention is to provide a colored contact lens with a pupil section, an iris section surrounding the pupil section, and a colored pattern over the iris section. The colored pattern can be generated by photographing a cosmetically appealing human eye, and then scanning the photographed human eye and storing the scanned image. Once stored, the scanned data can be separated into multiple component colors and patterns using separation software. The number of layers is merely that desired by the operator who commands the software used to separate out the requested number of colors and patterns from the recorded image of the human eye. A separate plate or cliché is created for each of the different color/pattern separations. These plates are then used during the printing of each of the different colors or layers onto the contact lens. The final lens contains all of the layers, colors and patterns and replicates the image of the human eye that was originally recorded. The colored contact lens is capable of changing the apparent color and color pattern of the iris of a person wearing the lens, while imparting a very natural appearance.

Another objective of a preferred embodiment of the invention is to provide a colored contact lens with a pupil section, an iris section surrounding the pupil section, and a colored pattern over the iris section. The colored pattern can be

generated by recording a cosmetically appealing human eye or a photograph of such an eye, and then separating the recorded image into multiple component colors and their associated patterns. The multiple color separations are then used to create the different portions used in the printing process to manufacture the colored lens. A separate design is created for each of the different portions consisting of the particular color separated out from the recorded image. Various processes can be used to apply each of the different designs onto the contact lens. The final lens contains all of the layers or colors and replicates the image of the human eye that was originally recorded. The colored contact lens is capable of changing the apparent color of the iris of a person wearing the lens, while imparting a very natural appearance.

It can be understood that many different colored portions can be created depending on the human eye or photograph of the human eye that is used in the process. Further, depending on the separation software utilized, different layers or portions may be developed from the same human eye image. Also, the final product may differ, even if the same image is used, depending on the number of colors or layers that are separated out from the image.

The term "ordinary viewer" is intended to mean a person having normal 20-20 vision standing from about 2 about 5 feet from a person wearing the lenses of this invention.

BRIEF DESCRIPTION OF THE DRAWINGS

The file of this patent contains at least one drawing or photograph executed in color. Copies of this patent with color drawings or photographs will be provided by the Patent and Trademark Office upon request and payment of the necessary fee.

Figure 1 illustrates a design for a contact lens in accordance with the present invention;

Figure 2 illustrates a colored image to be printed on a contact lens in accordance with the present invention;

Figure 3 illustrates a first component color of the image of Figure 2;

Figure 4 illustrates a second component color of the image of Figure 2;
Figure 5 illustrates a third component color of the image of Figure 2; and
Figure 6 illustrates a fourth component color of the image of Figure 2.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

Figure 1 shows a contact lens 10 in accordance with the present invention. It has a pupil section 20 in the center of lens, and an annular iris section 22 surrounding the pupil section. For hydrophilic or soft contact lenses, a peripheral section 24 surrounds iris section 22. A colored pattern 26 is located over the iris section 22. The pattern 26 is made up of multiple colored portions, each printed in its own pattern. The combination of these color patterns changes the apparent color and color pattern of the natural iris.

The pattern 26 located over the iris section 22 is created by combining multiple layers of different colored patterns together. To generate each of these multiple colored patterns, an image of a cosmetically pleasing eye (not shown) must first be recorded. The image of the eye can be photographed, painted, hand-drawn, printed or created by any well-known graphic design means. This includes chalk, pencil, ink, watercolor paintings, etc., as well as computer-created images.

The image is then recorded onto a medium such as a computer memory or the like. Recording the image can be accomplished by a number of different methods, such as scanning the image into the computer memory using a scanner, or capturing the image onto a computer memory or some other media using a digital camera, etc. The process of recording an image of the eye onto a computer memory may be one step, i.e., taking a picture of an eye with a digital camera.

Once the image of the cosmetically pleasing eye has been recorded or captured, the recorded image can optionally be enhanced using well-known means such as computer software like Adobe Photoshop.

Next, the recorded image may be separated into its component colors and their associated patterns. This separation of color patterns can be accomplished

in many ways, including using computer software, such as Adob Photoshop. The program separates the recorded image into its component colors or associated patterns. Each of the component color layers has a unique pattern that is dependent on the image of the eye that is being used, the computer program, and the operator's usage of the computer program. Each of the components can optionally be enhanced at this stage using any graphical arts methods.

Referring to Figures 2-6, an image for a finished contact lens pattern is shown with each of its color pattern components. Figure 2 is the finished image to be applied to the contact lens, and Figures 3-6 are the various color pattern components. The components can be printed on the lens (or on a film in a mold in which a lens is formed) in any order, although it is preferred to print Figure 3, then Figure 4, then Figure 5, then Figure 6.

Figure 3 shows a colored layer 30, which is the main color pattern separated out from a cosmetically pleasing eye photograph. In this example, colored layer 30 is blue, and it covers the iris section 22 and the peripheral section 24, but not the pupil section 20. In preferred embodiments, blue or green colors dominate the middle iris area. One preferred blue ink paste has the formulation:

Ingredient	Weight percent
Ethyl lactate	30.55
Binder soln.	61.15
PCN blue	1.21
TiO_2	7.09

One preferred green ink paste has the formulation:

Ingredient	Weight percent
Ethyl lactate	28.53
Binder soln.	63.85
PCN blue	0.03
Cr_2O_3	7.59

Figure 4 shows a colored layer 32 that covers, partially, iris section 22. Colored layer 32 is in a pattern known as an inner starburst. In the illustrated

embodiment, the inner starburst is hazel. One preferred hazel ink paste has the formulation:

Ingredient	Weight percent
Ethyl lactate	30
Binder soln.	63.49
PCN blue	0.06
I.O. Yellow	4.3
I.O. Red	1.54
TiO_2	0.61

Figure 5 shows a colored layer 34 that covers, partially, iris section 22. Colored layer 34 is in a pattern known as specks. In the illustrated embodiment, the specks were drawn with a computer mouse after color separations had been made from a recorded image. In one preferred embodiment, the specks are an enhanced violet color. One preferred violet ink paste has the following formulation:

Ingredient	Weight percent
Ethyl lactate	22.5
Binder soln.	76
Carbazole	1.5

Figure 6 shows a colored layer 36 that covers, partially, peripheral section 24. Colored layer 36 is in a pattern known as an outer starburst. In the illustrated embodiment, the outer starburst was drawn with a computer mouse after color separations had been made from a recorded image. In this example, colored layer 36 is black. One preferred black ink paste has the following formulation:

Ingredient	Weight percent
Ethyl lactate	23.98
Binder soln.	64.04
I.O. Black	11.98

All of the colors and their associated patterns ultimately combine to create a colored contact lens pattern simulating a cosmetically pleasing eye. In a

preferred embodiment, four color layers are used: a black layer, a hazel layer, a gray layer, and a blue or green layer.

To produce a pattern that is suitable for changing the appearance of the eye, it may be preferable to modify or alter either the recorded image, or some or all of the individual component color patterns. There are many different ways to effect such an alteration. Using software, the darker shades of the recorded image or the individual component colors may be removed to modify the final appearance. Also, the component colors can be converted into elements such as dots or islands of color. This conversion may ease the printing process as described below. Further, the colors separated out during the process may be associated with pigments and inks that have been previously approved by the Food and Drug Administration. Such alteration may facilitate the acceptance of the colored contact lens.

The recorded image or the individual component colors can be enhanced by adding colors and patterns such as radial lines and contrast zones (i.e., lighter annular zones). Additional layers may enhance the appearance of the eye even further. The modification or alteration may also be done by manipulating the patterns using the software that was used to separate out the colors and patterns initially, or by using mathematical algorithms such as a two-dimensional Fourier transform to modify the pattern. A device for Fourier transformations is disclosed in U.S. Patent No. 4,139,897, which is hereby incorporated by reference. Other enhancing techniques include but are not limited to using a computer program to paint, airbrush, halftone, sharp unmask, smudge, blur, defocus, tone, dodge, and sponge the recorded image.

Further, there are many other colors than those described above that can be separated out in accordance with the present invention. Other colors that can be separated from the cosmetically pleasing eye include brown, violet, cyan, magenta and yellow, among others. Further, the present invention is not limited to four layers making up the final pattern. In some cases, less than four colors may provide the amount of detail necessary. In some cases, depending on the software used to separate out the colored layers, more than four colors can be

combined to create a final pattern. If the designer determines, for example, that there are traces of violet in a blue cosmetically pleasing eye photograph, the designer may add yet another layer of violet, a fifth layer. This additional layer adds another printing step, but it may provide an even more pleasing colored contact lens.

Depending on the desired cosmetic effect, the coloring on the iris portion of the lens can be adjusted to let very little of the natural iris show through or to let a substantial portion show through. Showing the natural iris can be accomplished by making each component layer into a pattern of colored elements that are separated by clear or translucent spaces or by perforating one or more of the patterns with clear or translucent spaces. How much iris a user wants to show through the lens depends on whether the use wants to achieve a color enhancing effect or a color changing effect. The more natural iris that shows through, the more of a color enhancing effect is achieved. The less natural iris that shows through, the more of a color changing effect is achieved.

In one preferred embodiment, from about 0.1% to about 20% of a person's natural iris color shows through. In another preferred embodiment, from about 21% to about 50% of the natural iris shows through. The color can be adjusted to allow about 51% to about 75% to show through or even from about 76% to about 99% to show through.

Another way to determine how much natural iris shows through depends on how much coverage the colored patterns have over the contact lens. Coverage means the ratio of the area covered by colorant to the total area in a given analytical field that is entirely within the applied pattern annulus. There are many ways to analyze coverage. One preferred way is to use a Bausch & Lomb Omnicon 5000 Image Analyzer according to the instructions in the manual.

Producing the colored pattern onto the iris section 22 is preferably accomplished by printing the lens four times, each time with a different color layer, using the known printing process of Knapp's U.S. Pat. No. 4,582,402, incorporated herein by reference, and the known printing process of Rawlings' U.S. Patent No. 5,034,166, incorporated herein by reference and Rawlings U.S.

Patent No. 5,116,112, which was incorporated by reference above. Generally, a plate or cliché having depressions corresponding to the design generated in each colored layer, is smeared with ink of the desired shade. For example, Figure 3 shows the blue layer, generated by separating out the blue color from the cosmetically pleasing eye photograph. A plate corresponding to the blue layer would be smeared with blue ink.

Excess ink is then removed from the plate by scraping the surface of the plate with a doctor blade, leaving the depressions in the plate filled with ink, in this case hazel ink. A silicon rubber pad is then pressed against the plate to pick up the ink from the depressions, and then the pad is pressed against a surface of the lens to transfer the pattern to the lens. The printed pattern is then cured to render it unremovable from the lens. Of course, either the anterior or posterior surfaces of the lens may be printed, but printing the anterior surface is presently preferred.

Both the anterior and posterior sides of the lens may be printed on by directly or indirectly. One may print an ink directly onto the male or female or both molds, charging the mold with a monomer, engaging the molds, and curing the lens-forming monomer and the ink together. A combination of printing on the m old followed by printing on the cured lens may also be performed, preferably by printing on the female mold followed by printing on the cured lens. This is a convenient way of achieving a double-sided print.

As described above, the preferred embodiment contemplates printing four layers in a particular order. However, neither the order of layers nor the number of layers is be so limited.

In one preferred embodiment, a blue colored contact lens would be created by printing the four colored layers pertaining to a blue cosmetically pleasing eye photograph, namely, black, hazel, gray and blue.

The preferred lenses and ink ingredients used to practice this invention are known and described in Loshaek's U.S. Pat. No. 4,668,240, incorporated herein by reference. The specific ingredients and target weights are described in detail below. V ry briefly, a l ns constructed of polymer having -COOH, -OH, or

-NH_2 groups is printed with ink containing binding polymer having the same functional groups, opaque coloring substance, and a diisocyanate compound. First a mixture of binding polymer, pigments and solvent is prepared, and then mixed with more solvents and a diisocyanate to form an acceptable ink. The preferred binding polymer solutions have a viscosity of about 35,000 CPS for blue, gray, brown and black, and 50,000 CPS for green. The opaque ink is printed and cured on the lens surface. The lens chemistry need not be restricted to the above chemistry. For example, the system disclosed in Narducy, U.S. Patent No. 4,857,072, does not require the above-mentioned functional groups to impart a colorant onto a lens.

Ink pastes and pigments that can be used in the present invention can be made in a number of different ways using the ingredients and percentages (by weight) as described below in the ink color charts. An ink paste is normally combined with an adhesion promoter to make an ink.

For example, a hazel ink paste can be made using 63.49 percent binder solution (by weight), 30.00 percent ethyl lactate, 0.61 percent titanium dioxide, 0.06 percent PCN blue, 4.30 percent iron oxide yellow, and 1.54 percent iron oxide red. Although these colors are used for the preferred embodiments, other colors or variations of the weight percentage of ingredients may be used. The charts below are merely a representative example of the possible inks and pigment levels, and are not a complete list. One having ordinary skill in the art could develop other inks and pigment levels that would provide an enhancing effect to the iris of a person wearing the contact lens.

INK PASTE COLOR CODE	BLUE	GRAY
Ingredient	Weight Percent	Weight Percent
Ethyl Lactate	30.55	30.75
Binder Soln	61.15	59.84
PCN Blue	1.21	
PCN Green		0.23
TiO_2	7.09	7.34
IO Black		1.83

INK PASTE COLOR	BROWN	HAZEL
Ingredient	Weight Percent	Weight Percent
Ethyl Lactate	30.00	30.00
Binder Soln	55.10	63.49
PCN Blue		0.06
TiO_2		0.61
IO Black	5.70	
IO Red	3.45	1.54
IO Yellow		4.30
IO Brown	5.75	

INK PASTE COLOR	GREEN	BLACK
Ingredient	Weight Percent	Weight Percent
Ethyl Lactate	28.53	23.98
Binder Soln	63.85	64.04
PCN Blue	0.03	
IO Black		11.98
Cr_2O_2	7.59	

Clear pastes can be added to any of the above formulations to lighten the colors. This may produce a more natural looking color when a color change is sought instead of a color enhancement. Any hydrophilic polymer paste may be used as the clear paste. In a preferred embodiment, the clear paste is a 9:1 copolymer of 2-hydroxyethyl methacrylate (HEMA) to 2-ethoxyethyl methacrylate (EOEMA) in cyclopentanone thinned in ethyl lactate.

The ink formulations may be made to penetrate the surface of the lens to create a perception of depth. Such inks and lenses are described in GB 0384632.

The colored pattern may be deposited onto iris section of the lens in any manner. Currently preferred methods include by offset pad printing, described below in some detail. Other alternative methods include the use of a laser (U.S. Pat. No. 4,744,647) or an ink jet printer.

A plate (not shown) is prepared having a flat surface and circular depressions corresponding to the desired colored layer to be printed. The plate may be made by a technique that is well known for making integrated analog or digital circuits. First, a pattern about 20 times as large as the desired pattern is prepared. Next, the pattern is reduced using well-known photographic techniques to a pattern of the exact desired size having the portion to be colored darker than the remaining area. A flat surface is covered by a photo resist material that becomes water insoluble when exposed to light. The photo resist material is covered with the pattern and exposed to light. The portion of the photo resist pattern corresponding to the areas under the dark area of the pattern is removed by washing with water and the resulting plate is etched to the required depth. Then the remainder of the photo resist material is mechanically removed.

Colorant, comprising a pigment, binder or carrier for the pigment solvent and diisocyanate is deposited on the flat surface of the plate and scraped across the pattern with a doctor blade. This causes depressions to be filled with ink while removing excess ink from the flat surface.

A pad made of silicon rubber, impregnated with silicon oil for easy release, is pressed against the pattern, removing ink from the depressions. The ink on the pad is allowed to dry slightly to improve tackiness, then pressed against the front surface of the contact lens, depositing the ink in the desired pattern over the iris section. Of course the pad must have enough flexibility to deform to fit over the convex front surface of the lens. The printing step is repeated multiple times using the different color layer plates for each different color layer.

Next, the deposited layer is treated to render it resistant to removal from the lens under exposure to the ocular fluids that the lens will encounter when

placed in the eye. The exact method of preventing removal depends on the material of construction of the lens and the pattern. Mere air-drying or heating the lens may suffice. For hydrophilic lenses, the techniques for coating the opaque pattern described in Wichterle, U.S. Pat. No. 3,679,504 (incorporated herein by reference), may be used.

Although the steps listed above place an order to the printing of the different colored layers, the order of printing, and the number of printings, may not be important to the present invention and other orders of printing, or number of printings, would be covered by the present invention.

An alternative embodiment for printing the different layers on the iris section 22 of the contact lens provides for ink-jet printing instead of pad printing of each layer. Ink-jet printing is accomplished without the need of pads or plates and can be administered at a higher resolution than pad printing, thereby providing for greater detail of each colored layer and a more natural final pattern on the iris section 22 of the contact lens.

Using ink-jet printing also reduces the number of devices that make contact either with the contact lens or with other devices. For example, a silicon pad must make contact with a plate or cliché initially and then with the contact lens itself. Contact between the parts tends to wear down the parts which will then require replacements. During the ink-jet process, the micro-nozzles do not physically make contact with the contact lens, nor with any other device. The chance of the micro-nozzle wearing out is thereby reduced.

Further, the ink-jet printer is electronically controlled such that changing from one color layer to a different color layer can be done easily, by computer control. Thus, once the cosmetically pleasing eye photograph or picture has been recorded, stored and separated into its multiple colored layers, each layer can be applied to the colored contact lens using an ink-jet process, thereby creating a colored contact lens capable of changing the apparent color and color pattern of the wearer's iris.

If an ink jet printer is used, one of skill in the art should adjust the ink to optimize it for ink jet printing. For example, a preferred ink contains at least one

pigment. The pigment should be much smaller than an ink jet nozzle to prevent clogging during the printer process. Generally, this means that preferred pigments are 3 microns or smaller. Larger pigments can be ground into smaller particles to reduce potential clogging.

The preferred ink has a surface tension of at least 35 mN/m. Any surface tension parameter is acceptable so long as the ink jets adequately and spreads when it contacts the lens. Preferably, the ink breaks into well-defined streams of droplets based upon its surface tension. The surface tension of the ink can be adjusted by adding or removing diluents or surfactants.

A preferred ink has organic solvents. It can contain many solvents, including alcohols, glycols, ketones or esters. It is preferred, but not necessary, that the ink dry in less than 5 seconds. A preferred ink could optionally contain humectants (e.g., ethylene glyclol) and surfactants.

It is also preferred, for continuous ink jet operation, that the ink is charged by an electrode to drop away from the gutter and onto the printing surface. This can be achieved by many ways well known in the art, including by adding about 0.5% by weight of a salt.

The preferred ink flows easily in ink jet applications. Preferably, the ink has a viscosity of from about 1 centipoise to about 50 centipoise. More preferably, the viscosity is from about 2 to about 30 centipoise. Most preferably, the viscosity is between 5 and 15 centipoise.

The colorants can be printed in a single layer or in many layers, and in any pattern that achieves desirable cosmetic effects. Preferred patterns of colorants include those identified in U.S. Patent Nos. 5,936,705; 5,414,477; and 5,272,010, which are hereby incorporated by reference.

The patterns that the single or multiple layers of colorants form on the contact lenses are preferably comprised of zones, and the zones may be comprised of shaped colored regions within the zones. The shaped region may further be comprised of dots. Examples of zones include: a single annular iris color zone with irregular inner and outer borders, multiple concentric annular zones, annular zones with outer and inner starbursts, and a single iris zone but

irregular in structure along multiple radial lines. Examples of shaped colored areas within zones include circular areas, ovular regions, irregular elongated regions in worm-like shapes, radial segments, and combinations of these shapes

In a preferred embodiment, the colored contact lens is coated with a binding solution. Binding can occur during or after printing. It is preferred that the binding solution be applied to only those regions of the contact lens that are not in the optical zone.

The process of coating the contact lens can be done by any method that is well known in the art. In one embodiment, the binding solution could be sprayed onto the lens. If this method is used, a mask should be placed over the optical zone of the lens before spraying occurs. In another embodiment, the binding solution could be coated onto the lens using printing pads.

The preferred solvent of the binding solution depends upon the method of coating used. If the spraying method of coating is used, the solvent should have a low viscosity. That is, it is preferred that the viscosity be less than 50 centipoise. If the printing pad method of coating is used, the solvent should have a higher viscosity. That is, it is preferred that the viscosity be greater than 100 centipoise. Viscosity can be adjusted by the addition or subtraction of polymer chains or by the addition or subtraction of a solvent. Organic mixtures are the preferred solvents.

Preferably the binding solution comprises at least one monomer. More preferably, the binding solution comprises at least one hydrophilic monomer and at least one hydrophobic monomer.

Any hydrophilic monomer that can act as a plasticizer can be used. The hydrophilic monomer can allow the printed material to deform with the lens without cracking. Among the preferred hydrophilic monomers are 2-hydroxyethyl methacrylate (HEMA), NVP, GMA, and DMA.

Any hydrophobic monomer can be used to improve the strength of the lens and to improve the solubility of the monomer in organic solvents. Among the preferred hydrophobic monomers are 2-ethoxyethyl methacrylate (EOEMA), MMA, and BMA.

Preferably, the binding solution contains an initiator. Preferably, a UV or heat-activiting initiator is used.

Preferably, the binding solution makes a tightly cross-linked film that traps the colorants in the film. For this, it is preferable to add ethyleneglycol dimethacrylate. Swelling agents to allow penetration of the monomer into the contact lens and they improve adhesion. Preferred swelling agents include cyclopentanone or cyclohexanone.

Preferably, the binding solution contains an adhesion promotor. Preferably, the adhesion promotor is hexamethylene diisocyanate. Any adhesion promotor can be used, including those disclosed in U.S. Patent No. 5,272,010, which is incorporated by reference herein.

Preferably, the binding solution contains a chain transfer agent. Preferably, the chain transfer agent is mercaptoethanol.

Any ink jet printer can be used with the present invention so long as it can be configured to print the inks as described above on contact lenses that have curved surfaces.

A preferred ink jet printer is either drop-on-demand (DOD) or continuous-jet. A preferred ink jet printer can print pixels of less than 150 microns in diameter, preferably less than 100 microns in diameter. To achieve this result, it is preferred that the drops of ink that are emitted from the nozzle have a volume of less than 100 picoliters, preferably less than 50 picoliters, and more preferably, less than 10 picoliters. Pixel size is measured using standard microscopy techniques, which are well known to those of skill in the art.

A preferred ink jet nozzle is sized to form drops of the preferred volume given the ink viscosity and thermal forces. The ink jet printer head should be adjustable to account for the curved surface of the contact lens. Preferably, the nozzles can face perpendicular to the lens surfaces, forming a hemisphere around the lens. Alternatively, the lens surface could be rotated. It might also be usful to index the printer head with the lens rotator for non-radially symmetrical lenses with a non-symmetrical pattern.

In a preferred embodiment, the ink jet heads are controlled through the use of a computer.

In a preferred embodiment, batch processing could b used to print many contact lenses in rapid succession. For example, a batch of eight lenses (one palate) could be sent to eight printer heads. Lifts push the lens cup to put the in the vicinity of the printer heads. The cups could be rotated in a controlled fashion. The print heads would jet on and off based upon instructions sent from the computer software. The lifts would then lower the lenses back on their palate. Then, the palate would be sent through a system to print or spray the binding solution over the lenses. Then, the lenses would be sent to a curing process to heat and dry the lenses.

Information about ink jet printers and ink jet technology is readily available through vendors such as Domino-Amjet in Gurnee Mills, IL, as well as through "The Ink Jet Academy" which is held periodically in various locations throughout the world, including Barcelona, Spain and Orlando, Florida.

Through routine experimentation, one of ordinary skill in the art can optimize the process of printing colorants onto contact lenses using various quantifiable analytical techniques.

Opacity, or light reflectance can be optimized. The amount of light reflected by a solid ink pattern on a solid hydrogel can be measured to determine which dye/pigment combinations make the best colorant. The UV-Vis spectrompeter can quantify this information.

The surface tension of the inks can be monitored using a Denoy ring and the dyamic contact angle (DCA) apparatus. The adhesion of the ink to the contact lens can be tested using the FDA-required abrasion test. See the FDA web site for more information at http://www.fda.gov. To determine if there are residual monomers in the finished contact lens, HPLC, LC/MS data is insightful.

It may be preferable to treat the lens or a mold with a primer to demold the lens consistently so that the lens is on the male side of the mold after demolding to increase the adhesion of the ink to the surface or to enhance the hydrophilic ingredients that are introduced into the mold. Such primers are

described in U.S. Patent Nos. 5,158,718 and 5,894,002, which are incorporated herein by reference.

It can be seen that the present invention provides colored contact lenses capable of changing the appearance of the wearer's iris. Various changes may be made in the function and arrangement of parts: equivalent means may be substituted for those illustrated and described; and certain features may be used independently from others without departing from the spirit and scope of the invention as defined in the following claims.

Claims:

1. A method of designing a colored contact lens having a very natural appearance, comprising:
   a) recording an image of a cosmetically appealing eye; and
   b) separating the recorded image into a plurality of component colors and patterns that can be reproduced on a contact lens.

2. The method of Claim 1, wherein the image is an actual eye or a facsimile of an actual eye.

3. The method of Claim 2, wherein the facsimile of an actual eye is a photograph.

4. The method of Claim 1, wherein the image is created using graphic design means.

5. The method of Claim 4, wherein the graphic design means is selected from the group consisting of a software package, a pencil drawing, an ink drawing, a chalk drawing, a water-color painting, an oil painting, and combinations thereof.

6. The method of Claim 1, wherein the image is a graphically-enhanced facsimile of an actual eye.

7. The method of Claim 6, wherein the image is graphically enhanced using graphic design means.

8. The method of Claim 7, wherein the graphic design means is selected from the group consisting of a software package, a pencil drawing, an ink drawing, a chalk drawing, a water-color painting, an oil painting, and combinations thereof.

9. The method of Claim 8 wherein when the graphic design means is a software package, the graphical enhancements are achieved by a method selected from the group consisting of painting, airbrushing, halftoning, sharp unmasking, smudging, blurring, defocusing, toning, dodging, sponging, and combinations thereof.

10. The method of Claim 1, wherein the step of recording the image comprises scanning the image.

11. The method of Claim 10, wherein scanning comprises automatically storing the image in a computer memory.

12. The method of Claim 11, wherein storing the image in a computer memory comprises using a computer program.

13. The method of Claim 11, further comprising enhancing the recorded image.

14. The method of Claim 13, wherein enhancing is achieved using a computer program to perform tasks selected from the group consisting of painting, airbrushing, halftoning, sharp unmasking, smudging, blurring, defocusing, toning, dodging, sponging, and combinations thereof.

15. The method of claim 11 wherein the recorded image comprises elements having a particular density, the method further comprising varying the density of the elements.

16. The method of Claim 11, wherein the step of separating the recorded image comprises using a computer program to divide each component color or associated pattern from each other component color or associated pattern.

17. The method of Claim 16, wherein the component color comprises a color selected from the group consisting of brown, blue, gray, green, cyan, magenta, yellow, black, violet and hazel.

18. The method of Claim 1, wherein the plurality of component colors consists of four component colors.

19. The method of Claim 18, wherein the four component colors are black, hazel, gray and a color selected from the group consisting of brown, blue and green.

20. The method of Claim 18, wherein the four component colors are printed in the order comprising black, hazel, gray, and either blue, brown or green.

21. The method of Claim 1 further comprising altering at least one of the plurality of component colors.

22. The method of Claim 1 further comprising altering at least one pattern.

23. The method of Claim 1 wherein component color or pattern is reproduced on the contact lens by printing the color or pattern directly onto a contact lens.

24. The method of Claim 1 wherein component color or pattern is reproduced on the contact lens by printing the color or pattern onto a film in a mold used to make contact lens such that when the contact lens is formed in the mold, the film becomes part of the contact lens.

25. A method of manufacturing a colored contact lens having a very natural appearance, comprising:

a) recording an image of a cosmetically appealing eye;

b) separating the recorded image into a plurality of component colors; and

c) transferring each of the plurality of component colors onto a contact lens.

26. The method of Claim 25 further comprising altering at least one of the plurality of component colors.

27. The method of Claim 25, wherein transferring comprises:

a) providing a plurality of clichés for use in the pad printing process, wherein each cliché corresponds to each of the plurality of component colors;

b) applying one of a plurality of component color inks to each of the clichés, wherein each of the plurality of component color inks corresponding to each of the plurality of component colors;

c) coating a plurality of pads with each of the plurality of component color inks, wherein each of the plurality of pads corresponding to each of the clichés;

d) placing each of the plurality of pads in direct contact with a contact lens, such that the contact lens obtains each of the plurality of component color inks, thereby manufacturing a color contact lens having a very natural appearance.

28. The method of Claim 25, wherein transferring comprises:

a) providing a plurality of clichés for use in the pad printing process, wherein each cliché corresponds to each of the plurality of component colors;

b) applying one of a plurality of component color inks to each of the clichés, wherein each of the plurality of component color inks corresponding to each of the plurality of component colors;

c) coating a plurality of pads with each of the plurality of component color inks, wherein each of the plurality of pads corresponding to each of the clichés;

d) placing each of the plurality of pads in direct contact with a film in a mold such that when a contact lens is formed in the mold, the film becomes part of the contact lens, thereby manufacturing a color contact lens having a very natural appearance.

29. The method of Claim 25, wherein transferring comprises applying each of the plurality of component color inks in a corresponding color design, to the contact lens, using an ink-jet printer, thereby manufacturing a color contact lens having a very natural appearance.

30. The method of Claim 25, wherein transferring comprises applying each of the plurality of component color inks in a corresponding color design, to the contact lens, using an ink-jet printer, thereby manufacturing a color contact lens having a very natural appearance.

31. The method of Claim 25, wherein transferring comprises printing each of the plurality of component color inks onto a surface in a casting mold, forming the contact lens therein, and removing the contact lens from the mold such that the surface in the casting mold becomes attached to the contact lens before the lens is removed from the mold.

32. A colored contact lens comprising:
a pupil section;
an iris section surrounding the pupil section; and
a colored intermittent pattern made up of a plurality of component colors and designs located over the entire iris section, the pattern covering an effective amount of the iris section to change the apparent color and color pattern of the iris, the pattern comprising:
a plurality of component colors, each of the plurality of component colors corresponding to a particular design, each of the plurality of component colors and particular designs corresponding to a component color and particular designs in an actual eye, wherein each of the component colors and particular designs is determined

by recording an image of a cosmetically appealing eye, separating the image of the recorded image into the plurality of component colors and particular designs, and transferring the plurality of component colors and particular designs to a contact lens, thereby creating a contact lens having a very natural appearance.

33. The lens of Claim 32 wherein from about 0.1% to about 20% of a person's natural iris color shows through the lens.

34. The lens of Claim 32 wherein from about 21% to about 50% of a person's natural iris color shows through the lens.

35. The lens of Claim 32 wherein from about 51% to about 75% of a person's natural iris color shows through the lens.

36. The lens of Claim 32 wherein from about 76% to about 99% of a person's natural iris color shows through the lens.

ABSTRACT OF THE DISCLOSURE

A colored contact lens and a method of making same is provided. An image of an eye is recorded, optionally enhanced, separated into color pattern components, optionally enhanced, then each color pattern component printed on a contact lens, directly or indirectly. The end result is a natural looking contact that enhances the natural iris color or changes the apparent color of the natural iris.

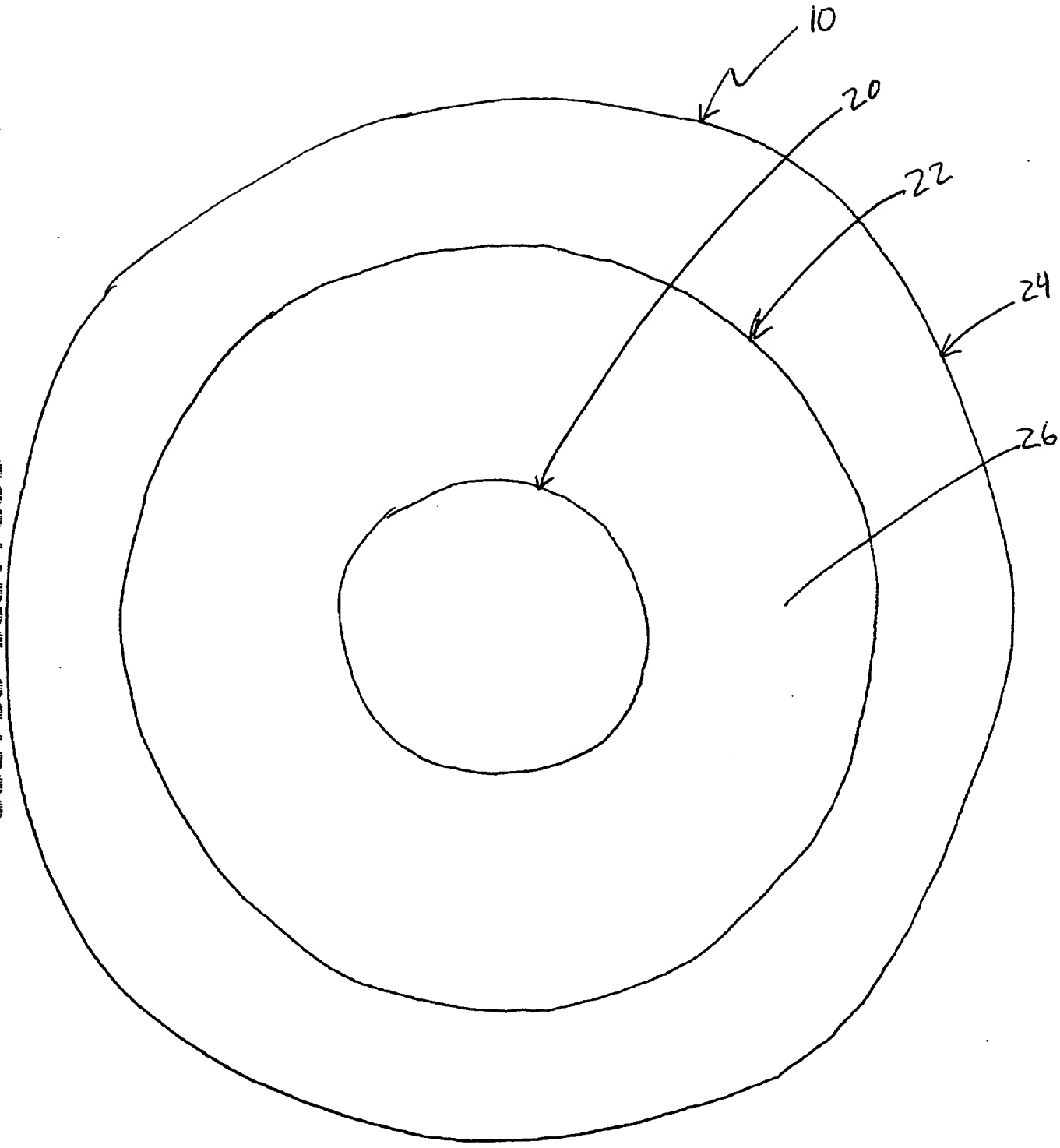
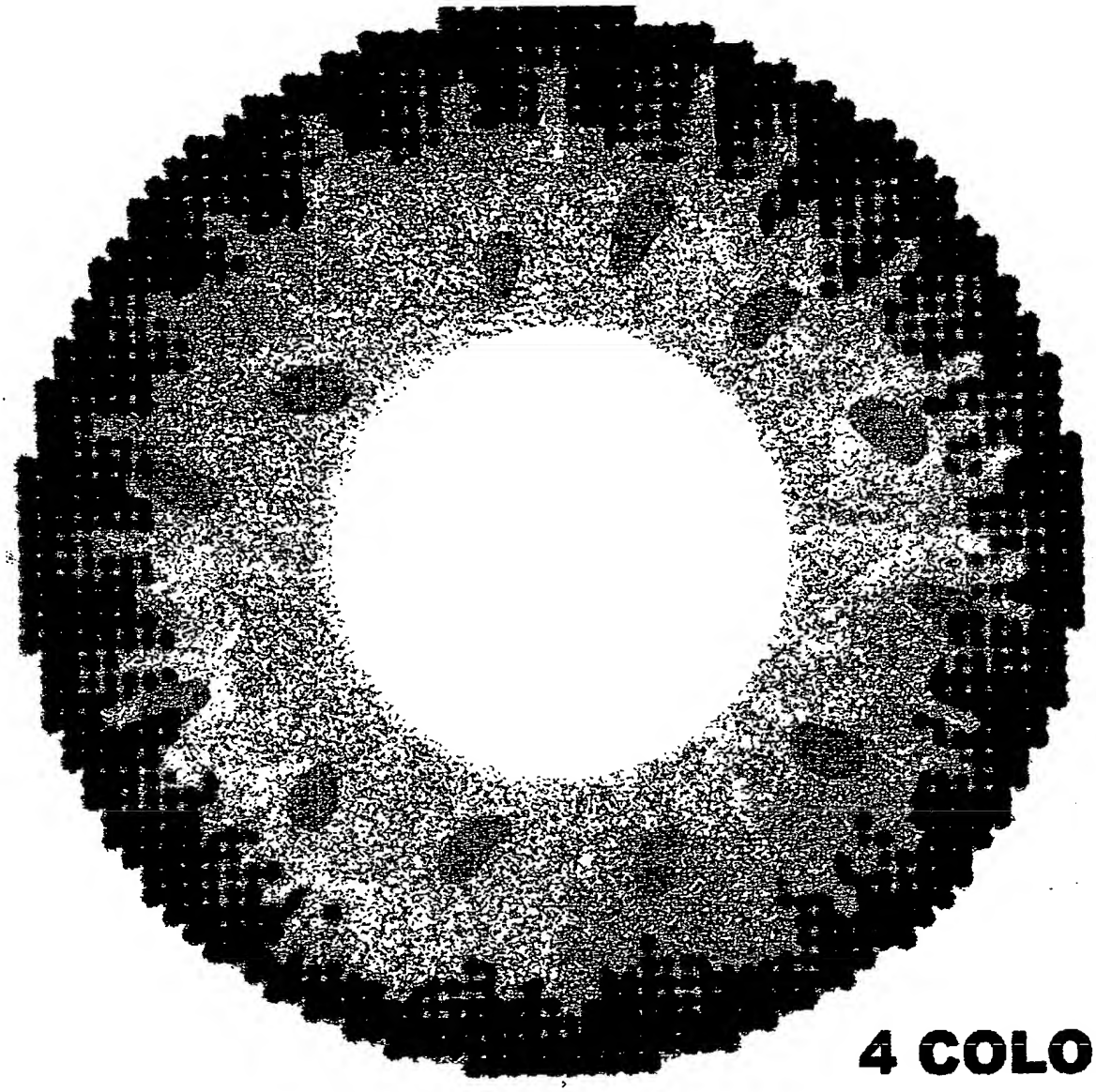
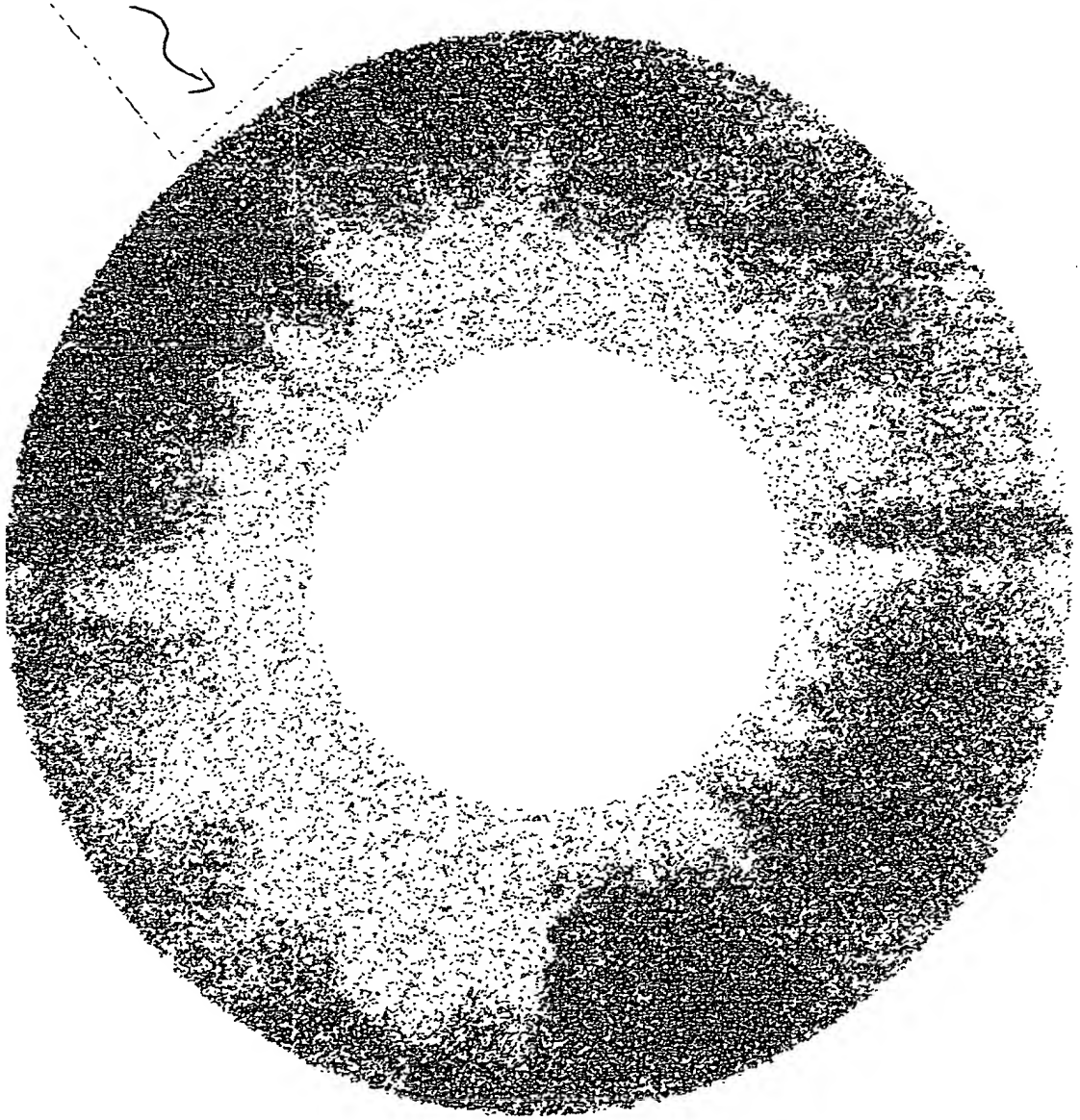


FIGURE 1



4 COLORS

Fig. 2

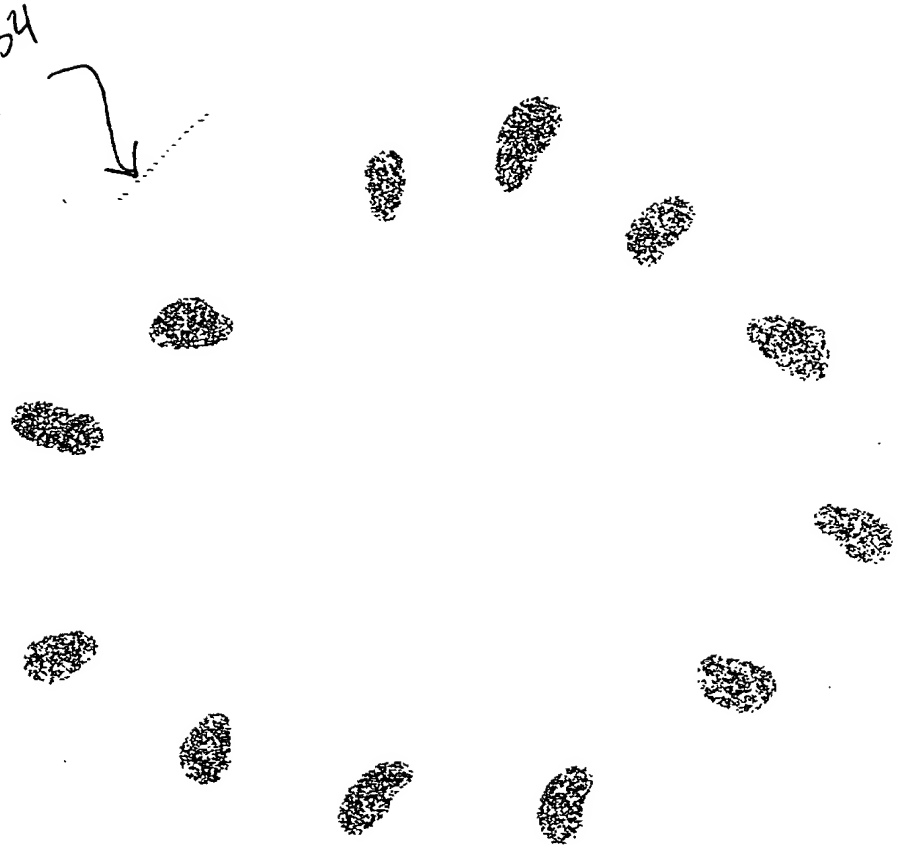


MAIN COLOR

Fig. 3

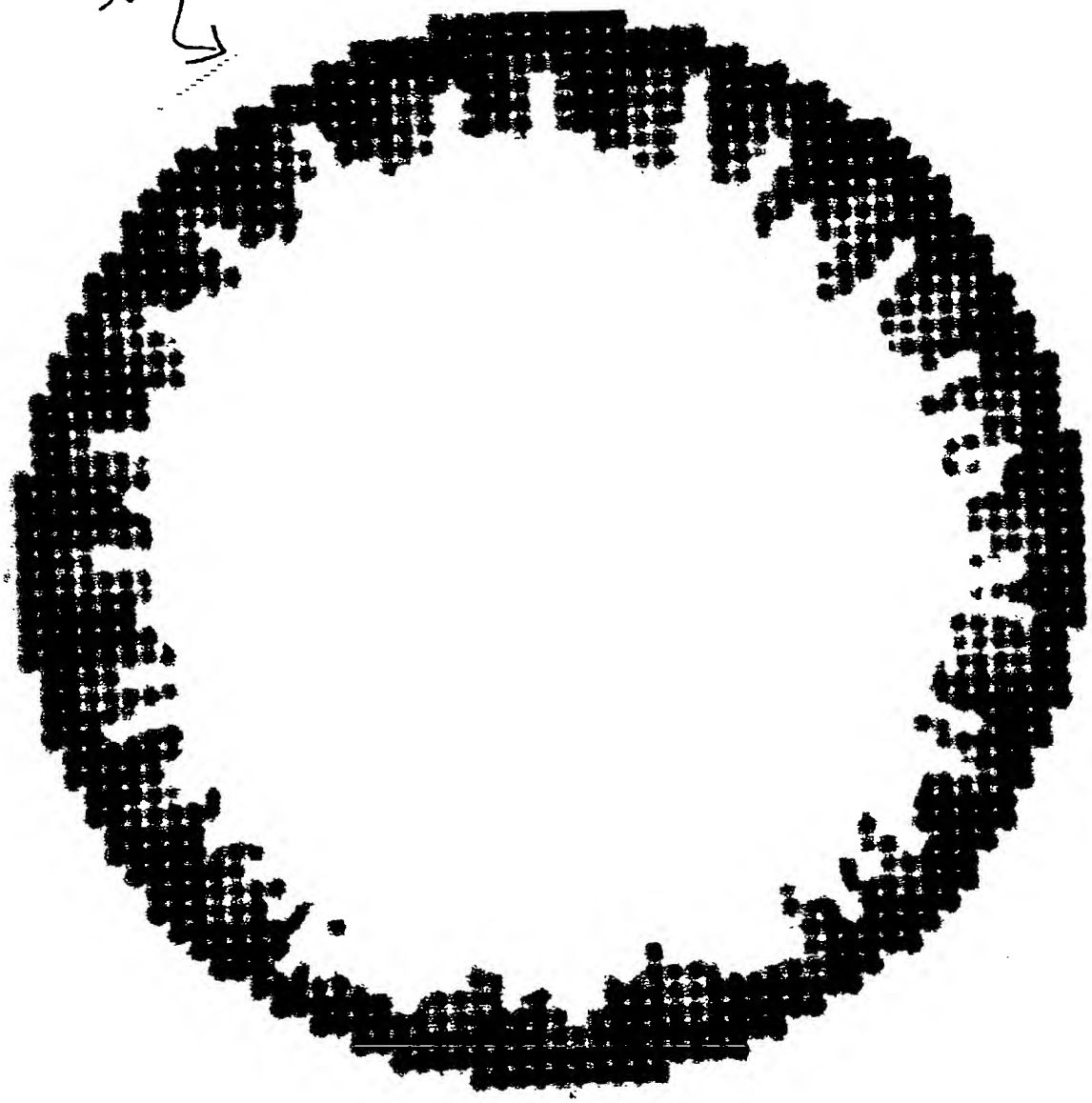
INNER STARBUST

Fig. 4



SPECKS

Fig. 5



OUTER STARBUST

Fig. 6

"Express Mail" mailing label number EL 337743512 US 06-23-00 H/RKOV
Date of Deposit June 20, 2000

PROVISIONAL APPLICATION COVER SHEET

This is a request for filing a PROVISIONAL APPLICATION under 37 CFR 1.53(c).

Docket Number	7651-1519	Type a plus sign (+) inside this box	+

INVENTOR(S)/APPLICANT(S)			
Last Name	First Name	Middle Initial	Residence (City And Either State Or Foreign Country
Tucker	Robert	C.	Arlington Heights, Illinois

TITLE OF INVENTION (280 characters max)

DIGITAL PRINTING CONTACT LENSES

CORRESPONDENCE ADDRESS

Linda D. Kennedy, Esq.
BRINKS HOFER GILSON & LIONE
P.O. Box 10395
Chicago, IL 60610

STATE		ZIP CODE		COUNTRY	

ENCLOSED APPLICATION PARTS (check all that apply)

☒ Specification	Number of Pages	20	☐ Small Entity Statement
☒ Drawing(s)	Number of Sheets	2	☐ Other (specify)

METHOD OF PAYMENT (check one)

☒ A check or money order is enclosed to cover the Provisional filing fees.	PROVISIONAL FILING FEE AMOUNT(S)	150.00
☐ The Commissioner is hereby authorized to charge filing fees and credit Deposit Account Number 23-1925		

The invention was made by an agency of the United States Government or under a contract with an Agency of the United States Government.

☒ No.
☐ Yes, the name of the U.S. government agency and the Government contract number are:_____.

Respectfully submitted,

SIGNATURE: Linda D. Kennedy
TYPED OR PRINTED NAME: Linda D. Kennedy

Date: June 20, 2000
Registration No. 44,183 (if appropriate)

☐ Additional inventors are being named on separately numbered sheets attached hereto.

PROVISIONAL APPLICATION FILING ONLY

Burden Hour Statement This form is estimated to take 2 hours to complete Time will vary depending upon the needs of the individual case Any comments on the amount of time you are required to complete this form should be sent to the Office of Assistance Quality and Enhancement Division, Patent and Trademark Office, Washington, DC 20231, and to the Office of Information and Regulatory Affairs, Office of Management and Budget (Project 0651-0037), Washington, DC 20503 DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS SEND TO Assistant Commissioner for Patents, Washington, DC 20231

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Case No. 7651/1519
Wesley-Jessen Corporation No. 5049

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
PROVISIONAL APPLICATION FOR UNITED STATES LETTERS PATENT

INVENTOR: ROBERT C. TUCKER
719 N. Kaspar Avenue
Arlington Heights, IL 60004

TITLE: PRINTING COLORED CONTACT LENSES

ATTORNEYS: LINDA D. KENNEDY
Reg. No. 44,183
STEVEN P. SHURTZ
Reg. No. 31,424
BRINKS HOFER GILSON & LIONE,
INTELLECTUAL PROPERTY ATTORNEYS
NBC TOWER - SUITE 3600
455 NORTH CITYFRONT PLAZA
CHICAGO, ILLINOIS 60611

PRINTING COLORED CONTACT LENSES

BACKGROUND

For cosmetic purposes, contact lenses having one or more colorants dispersed in the lens or printed on the lens are in high demand. These colored contact lenses enhance the natural beauty of the eye, or provide unique patterns on the iris of the wearer.

Presently, methods of printing inks onto contact lenses involve cliché ink transfer printing. A typical example of this printing follows. An image is etched into metal to form a cliché. The cliché is placed on a printer. Once on the printer, the cliché is inked by either an open inkwell doctoring system or by a closed ink cup sliding across the image. Then, a silicone pad picks up the inked image from the cliché and transfers the image to the contact lens. The silicone pads are made of a material comprising silicon that can vary in elasticity. The properties of the silicone material permit the inks to stick to the pad temporarily and fully release from the pad when it contacts the contact lens.

There are several disadvantages associated with using cliché ink transfer printing to color contact lenses. This method lacks consistency. Slight differences in the silicone pad can cause wide variation in image quality, effecting dot resolution and color reproducibility. Further, multiple color layering is difficult and time consuming. Further still, the design and printing process using this method is slow. After an image is fully designed, it can take about two weeks before that image is etched onto a cliché. The set-up is painstakingly detailed and lengthy when more than one color is going to be printed on the lens using this method. Presently, only three overlays of color can be applied using this printing method. The difficulty and slowness of this printing method inhibits business strategies, making it difficult to offer consumers a chance to design and print their own contact lenses at the point of purchase.

A printing apparatus and printing method are needed that can produce high quality images in a consistent manner on contact lenses. A simple, quick, and highly precise printing apparatus and method are needed when multiple

colors are being printed onto a contact lens, preferably one that permits consumers to design and print their own contact lenses when they purchase those lenses.

SUMMARY OF THE INVENTION

The products and processes of the present invention address at least some of the difficulties in the prior art.

In one aspect of the invention, a method of making a colored contact lens comprises printing at least one layer of a colorant onto a contact lens using a printing process selected from the group consisting of ink jet printing, electrophotographic printing, thermal transfer, and photographic development.

In another aspect of the invention, a method of making a colored contact lens comprises: (a) printing a first layer of a colorant in a first pattern onto a contact lens using a printing process selected from the group consisting of ink jet printing, electrophotographic printing, thermal transfer, and photographic development; (b) printing at least one second layer of a colorant in a second pattern onto a contact lens using a printing process selected from the group consisting of ink jet printing, electrophotographic printing, thermal transfer, and photographic development; and (c) coating the colored contact lens with a binding solution comprising a monomer or a polymer.

In still another aspect of the invention, an improved method of making colored contact lenses comprises printing at least one layer of a colorant onto a contact lens using a printing process selected from the group consisting of ink jet printing, electrophotographic printing, thermal transfer, and photographic development.

The present invention provides the foregoing and other features, and the advantages of the invention will become further apparent from the following detailed description of the presently preferred embodiments, read in conjunction with the accompanying figures. The detailed description and figures are merely illustrative of the invention and do not limit the scope of the invention, which is defined by the appended claims and equivalents thereof.

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1 shows electrophotographic printing onto contact lenses using a photosensitive sphere.

Figure 2 shows electrophotographic printing onto contact lenses using a photosensitive hemisphere.

Figure 3 shows thermal transfer printing onto contact lenses.

Figure 4 shows a top view of the thermal transfer printing of Figure 3.

Figure 5 shows a cross section of the lens in Figure 23 after it has been printed on using thermal transfer printing.

Figure 6 shows photographic transfer printing onto contact lenses.

Figure 7 shows an image printed onto a contact lens by photographic transfer printing.

DETAILED DESCRIPTION

DEFINITIONS

"Colorant" means either a dye or a pigment or a mixture thereof.

"Dye" means a substance that is soluble in a solvent and that is used to impart color. Dyes are typically translucent and absorb but do not scatter light. Dyes can cover both optical regions of contact lenses and non-optical regions of contact lenses.

"Fluorescence" means luminescence caused by absorption of visible light or ultraviolet radiation at one wavelength followed by nearly immediate emission at a longer wavelength. Fluorescent emission ceases almost immediately when the light or incident ultraviolet radiation stops.

"Monomer" means low molecular weight compounds that can be polymerized. Low molecular weight typically means average molecular weights less than 700 Daltons. The term "monomer" also refers to medium and high molecular weight compounds or polymers, sometimes referred to as

macromonomers, (that is, typically having number average molecular weights greater than 700) containing functional groups capable of further polymerization.

"Pearlescence" means having a pearly luster; resembling a pearl in physical appearance; or having a nearly neutral slightly bluish medium gray color.

"Phosphorescence" is luminescence caused by the absorption of radiation at one wavelength followed by delayed emission at a different wavelength. Phosphorescent emission continues for a prolonged time after the incident radiation stops.

"Pigment" means a powdered substance that is suspended in a liquid in which it is relatively insoluble. Pigments are used to impart color. Because pigments are in the form of a suspension, they tend to have an opacity quality. That is, they reflect light and obstruct the passage of light. For this reason, it is preferred that pigments are located in non-optical regions of a contact lens.

"Polymer" means a material formed by polymerizing one or more monomers.

THE CONTACT LENSES

The methods of the present invention involve printing a colorant onto a contact lens using ink jet printing, electrophotographic printing, thermal transfer, or photographic development. The image is preferably a digital image, but it can also be an analog image.

In one embodiment, the contact lenses are transparent before they are printed upon. In another embodiment, the contact lenses are tinted prior to being printed upon. That is, a colorant may have been dispersed in that lens using methods that are well known in the art before that lens is printed upon using digital technology.

In another embodiment, the contact lenses that are going to be printed upon can optionally have been pre-printed using methods that are well known in the art. The well known methods include the ones disclosed in U.S. Patent No. 5,116,112, which is hereby incorporated by reference. This method involves

coating a colored liquid (which is either thermosetting or thermoplastic) in a mold for making a contact lens onto a surface thereof where the iris portion of the lens is formed to produce a colored film providing a pattern thereon which film contains a surface exposed to the interior of the mold and a surface in contact with the mold; and charging the mold with the lens-forming liquid used to form the body of the lens while maintaining the colored film in the iris portion and configuring the lens-forming liquid about the colored film whereby the surface of the film becomes integral with the body of the lens and surface of the film becomes part of the outer surface of the lens when the molded lens is removed from the mold.

INK JET PRINTING

Preferably, the colorant applied to the contact lens using an ink jet printer is an ink. A preferred ink contains at least one dye. Nearly any dye can be used in the present invention, so long as it can be used in an ink jet printer. These dyes include fluorescent dyes, phosphorescent dyes, pearlescent dyes, and conventional dyes.

A preferred ink contains at least one pigment. Nearly any pigment can be used in the present invention, so long as it can be used in an ink jet printer. Preferred pigments include fluorescent pigments, phosphorescent pigments, pearlescent pigments, and conventional pigments. Pigments can include any colorant permitted in medical devices and approved by the FDA, such as D&C Blue No. 6, D&C Green No. 6, D&C Red No. 17, D&C Violet No. 2, D&C Yellow No. 10, carbazole violet, certain copper complexes, certain chromium oxides, various iron oxides, phthalocyanine green, titanium dioxides, etc. See Marmiom DM Handbook of U.S. Colorants for a list of colorants that may be used with the present invention.

The pigment should be much smaller than an ink jet nozzle to prevent clogging during the printer process. Generally, this means that preferred pigments are 3 microns or smaller. Larger pigments can be ground into smaller particles to reduce potential clogging. Preferred methods of reducing a

pigment's particle size include high speed mixers, Kady Mills, colloid mills, homogenizers, microfluidizers, sonalators, ultrasonic mills, roll mills, ball mills, roller mills, vibrating ball mills, attritors, sand mills, varikinetic dispensers, three-roll mills, Banbury mixers, or other methods well known to those of skill in the art.

The preferred ink has a surface tension of at least 35 mN/m. Any surface tension parameter is acceptable so long as the ink jets adequately and spreads when it contacts the lens. Preferably, the ink breaks into well-defined streams of droplets based upon its surface tension. The surface tension of the ink can be adjusted by adding or removing diluents or surfactants.

It is preferred, but not necessary, that the ink dry in less than 5 seconds. It is preferred that the ink adhere to the lens and that the lens retain its shape after autoclave.

A preferred ink has organic solvents. Preferred solvents require some polarity to dissolve a binder. Preferred solvents have few functional groups that compete with the isocyanate cross-linking system such as alcohol groups, amine groups, and acid groups. A preferred ink can contain many solvents, including glycols, ketones or esters. Cyclopentanone is a particularly preferred solvent. A preferred ink could optionally contain humectants (e.g., ethylene glyclol) and surfactants.

It is also preferred, for continuous ink jet operation, that the ink is charged by an electrode to drop away from the gutter and onto the printing surface. This can be achieved by many ways well known in the art, including by adding about 0.5% by weight of a salt.

The preferred ink flows easily in ink jet applications. Preferably, the ink has a viscosity of from about 1 centipoise to about 50 centipoise. More preferably, the viscosity is from about 2 to about 30 centipoise. Most preferably, the viscosity is between 5 and 15 centipoise.

The colorants can be printed in a single layer or in many layers, and in any pattern that achieves desirable cosmetic effects. Preferred patterns of colorants include those identified in U.S. Patent Nos. 5,936,705; 5,414,477; and 5,272,010, which are hereby incorporated by reference.

The patterns that the single or multiple layers of colorants form on the contact lenses are preferably comprised of zones, and the zones may be comprised of shaped colored regions within the zones. The shaped region may further be comprised of dots. Examples of zones include: a single annular iris color zone with irregular inner and outer borders, multiple concentric annular zones, annular zones with outer and inner starbursts, and a single iris zone but irregular in structure along multiple radial lines. Examples of shaped colored areas within zones include circular areas, ovular regions, irregular elongated regions in worm-like shapes, radial segments, and combinations of these shapes

The addition of surfactants, particularly ionic surfactants may be helpful for optimal color dispersion.

In a preferred embodiment, the colored contact lens is coated with a binding solution. Binding can occur during or after printing. It is preferred that the binding solution be applied to only those regions of the contact lens that are not in the optical zone, or the zone of the contact lens through which one sees.

The process of coating the contact lens can be done by any method that is well known in the art. In one embodiment, the binding solution could be sprayed onto the lens. If this method is used, a mask should be placed over the optical zone of the lens before spraying occurs. In another embodiment, the binding solution could be coated onto the lens using printing pads.

The preferred solvent of the binding solution depends upon the method of coating used. If the spraying method of coating is used, the solvent should have a low viscosity. That is, it is preferred that the viscosity be less than 50 centipoise. If the printing pad method of coating is used, the solvent should have a higher viscosity. That is, it is preferred that the viscosity be greater than 100 centipoise. Viscosity can be adjusted by the addition or subtraction of polymer chains or by the addition or subtraction of a solvent. Organic mixtures are the preferred solvents.

Preferably the binding solution comprises at least one monomer. More preferably, the binding solution comprises at least one hydrophilic monomer and at least one hydrophobic monomer.

Nearly any hydrophilic monomer that can act as a plasticizer can be used. The hydrophilic monomer can allow the printed material to deform with the lens without cracking. Among the preferred hydrophilic monom rs are 2-hydroxyethyl methacrylate (HEMA), n-vinylpyrolidone (NVP), glycerylmethacrylate (GMA), and N,N-dimethyacrylamide (DMA). This list is exemplary, not limiting.

Nearly any hydrophobic monomer can be used to improve the strength of the coating and to improve the solubility of the monomer in organic solvents. Among the preferred hydrophobic monomers are 2-ethoxyethyl methacrylate (EOEMA), methyl methacrylate (MMA), and n-butyl methacrylate (BMA). This list is exemplary, not limiting.

Preferably, the binding solution contains an initiator. Preferably, a UV or heat-activiting initiator is used.

Preferably, the binding solution makes a tightly cross-linked film that traps the colorants in the film. For this, it is preferable to add ethylene glycol dimethacrylate. Hexamethylenediisocyanate (HMDI) is another preferred crosslinker. This list is exemplary, not limiting. Swelling agents to allow penetration of the monomer into the contact lens and they improve adhesion. Preferred swelling agents include cyclopentanone, cyclohexanone, or methyl ethyl ketone. This list is exemplary, not limiting.

Preferably, the binding solution contains an adhesion promoter. Preferably, the adhesion promoter is HMDI. Nearly any adhesion promoter can be used, including those disclosed in U.S. Patent No. 5,272,010, which is incorporated by reference herein.

Preferably, the binding solution contains a chain transfer agent. Preferably, the chain transfer agent is mercaptoethanol.

Any ink jet printer can be used with the present invention so long as it can be configured to print the inks as described above on contact lenses that have curved surfaces. The TRIDENT OPTIJET 2 printhead is a preferred printhead available from the Trident Corp. in Park Ridge, Illinois.

A preferred ink jet printer is either drop-on-demand (DOD) or continuous-jet. Many continuous ink jet printers could be used from companies such as

Domino-Amjet, Videojet, Scitex Digital Printing, Willet, Linx, Iris Graphics, Stork, an Dupont. Many DOD printers could be used from companies such as Epson, Xaar, Hitachi, Spectra, Tektronix, Canon, Hewlett-Packard, Lexmark, Olivetti, Xerox, Panasonic, VUTEk, and NEC.

A preferred ink jet printer can print pixels of less than 150 microns in diameter, preferably less than 100 microns in diameter. Pixel size is measured using standard microscopy techniques, which are well known to those of skill in the art. A preferred ink jet printer can space the pixels less than 80 microns from each other, preferably less than 50 microns from each other. To achieve this result, it is preferred that the drops of ink that are emitted from the nozzle have a volume of less than 100 picoliters, preferably less than 50 picoliters, and more preferably, less than 10 picoliters.

A preferred ink jet nozzle is sized to form drops of the preferred volume given the ink viscosity and thermal forces. Preferably, the nozzles can face perpendicular to the lens surfaces, forming a hemisphere around the lens. Alternatively, the lens surface could be rotated. It might also be usful to index the printer head with the lens rotator for non-radially symmetrical lenses with a non-symmetrical pattern.

In a preferred embodiment, the ink jet heads are controlled through the use of a computer.

In a preferred embodiment, batch processing could be used to print many contact lenses in rapid succession. For example, a batch of eight lenses (one palate) could be sent to eight printer heads. Lifts push the lens cup to put it in the vicinity of the printer heads. The cups could be rotated in a controlled fashion. The print heads would jet on and off based upon instructions sent from the computer software. The lifts would then lower the lenses back on their palate. Then, the palate would be sent through a system to print or spray the binding solution over the lenses. Then, the lenses would be sent to a curing process to heat and dry the lenses.

Through routine experim ntation, one of ordinary skill in the art can optimize the process of printing colorants onto contact lenses using various quantifiable analytical techniques.

ELECTROPHOTOGRAPHIC PRINTING

Electrophotographic printing includes laser printing. Referring to Figure 1, a preferred embodiment is shown. A toner drum 8 transmits toner to contact lens 6 via a photosensitive metal sphere 9. In this embodiment, metal sphere 9 rolls over contact lens 6.

Referring to Figure 2, a toner drum 18 transmits toner to a photosensitive metal hemisphere 19. In this embodiment, lens 16 is placed over the hemisphere 19 after the toner has been printed on the hemisphere 19. The lens 16 is printed on an internal surface.

Generally, electrophotographic printing works as follows. A computer-controlled light source (laser 4 in Figure 1, laser 14 in Figure 2) in electrical communication with an RGB (red, green, blue) signal (signal 2 in Figure 1, signal 12 in Figure 2) is directed to a photosensitive drum (drum 8 in Figure 1, drum 18 in Figure 2), which attracts charged toner particles where exposed.

Print quality is adjusted by varying the charge to attract different concentrations of toner. The toner is then transferred by rolling the contact lens across the drum using rollers.

For contact lenses, the photosensitive metal sphere 9 or hemisphere 19 could be used instead of the more traditional photosensitive drum. Light would be used to charge the sphere 9 or hemisphere 19. Toner particles, one color at a time, would then be exposed to the sphere 9 or hemisphere 19. The sphere 9 or hemisphere 19 could then contact a surface of a contact lens 6 or contact lens 16 to transfer the toner to a surface, either external or internal, of the contact lens 6 or 16.

Alternatively, the lens could contain a photoconductive monomer such as vinyl carbazol. This would allow the lens to be placed directly on the photosensitive hemisphere 19. Light would charge the lens surface directly to

allow toner particle transfer without the need for an additional toner transfer process.

Compressional forces (via rollers, balls, molds, etc.) could be used to facilitate toner transfer. Adhesive agents such as those that are well known in the art could be added before or after printing to ensure colorfastness.

THERMAL TRANSFER

Referring to Figures 3-5, one embodiment of thermal transfer is shown. An RGB signal 22 is in communication with thermal head 24. Thermal head 24 allows heat to pass through a donor ribbon 27, allowing the color of donor ribbon 27 to pass onto contact lens 26. In the depicted embodiment, donor ribbon 27 has three sections wherein the first second is yellow, the second section is magenta, and the third section is cyan so that only one color is transferred to the contact lens 26 at a time. In another embodiment, there could be one ribbon for each color that is to be printed. Donor ribbon 27 is supported on spools or rollers 23 and 25.

Figure 4 is a top view of Figure 3 taken along line 4-4. Figure 5 is a cross section of contact lens 26 taken along line 5-5 after it has been printed upon using thermal transfer. Layer 26 is the contact lens, layer 31 is yellow, layer 32 is magenta, and layer 33 is cyan. In an alternative embodiment, the order in which the color layers are printed onto the contact lens is alternated.

Thermal transfer technology relies upon the transfer of image-forming dyes or colored waxes onto a substrate such as a contact lens 26 or a film for use in a mold where a contact lens is formed. An analog image or a digital computer image desired is broken into its RGB constituents using standard color separation techniques.

A three-color complement system such as CMY (cyan, magenta, and yellow) can be used as the colorant media to absorb the corresponding color (cyan absorbs red, etc.). Each color layer is broken down into a raster signal, which controls a thermal head 24 that sequentially passes over a cyan, magenta, and yellow dye or wax donor ribbon 27. Applying heat causes the donor ribbon

27 to transfer its colorant onto the substrate (either contact lens 26 or a film for use in a mold where a contact lens is formed) passing underneath the ribbon 27. After passing over all three sections of ribbon 27, a three-layered surface is formed on the substrate (contact lens) composed of the different colors, as shown in Figure 5. Process color could be used to form secondary and tertiary colors.

The ribbon 27 may be flat (typical of printing onto flat substrates) and rolled across the surface of the lens using rollers. A preferred method would use a curved hemispherical-shaped ribbon to facilitate printing on the hemispherical contact lenses.

PHOTOGRAPHIC DEVELOPING

Referring to Figures 6 and 7, a digital displayed image 40 is reproduced as an image 44 printed onto contact lens 36. Light burns the image 40 onto film 35. Film 35 has three light-sensitive layers. Layer 37 is blue sensitive, layer 38 is green sensitive, and layer 39 is red sensitive. The contact lens is then chemically treated using film developing processes well known in the art. Layer 37, which is blue sensitive, forms as much of its complementary color (yellow) as layer 37a as is necessary to reproduce image 40. Likewise, layer 38, when processed, forms its complementary color as layer 38a, and layer 39 forms its complementary color as layer 39a. Excess material not necessary for reproduction of the image 40 is either washed away during chemical treatment or is clear after chemical treatment.

Photosensitive dyes may be used for digital image capturing, similar to the well-known technology used for photographic transparencies. A film composed of three light-sensitive layers (corresponding to blue, green, and red) is deposited on the contact lens surface or the surface of a film for use in a mold where a contact lens is formed.

A computer-controlled light source (such as a cathode-ray tube) is used to expose the color-sensitive layers. The film is then chemically processed to form the complementary colors to be presented on the surface being printed upon.

The chemical processing or film development is done using technology that is well known in the art.

SCOPE

It can be seen that the present invention provides colored contact lenses capable of changing the appearance of the wearer's iris. Various changes may be made in the function and arrangement of parts: equivalent means may be substituted for those illustrated and described; and certain features may be used independently from others without departing from the spirit and scope of the invention as defined in the following claims.

Claims:

1. A method of making a colored contact lens, the method comprising printing at least one layer of a colorant onto a contact lens using a printing process selected from the group consisting of ink jet printing, electrophotographic printing, thermal transfer, and photographic development.

2. The method of claim 1 wherein the printing process is ink jet printing.

3. The method of claim 2 where in the colorant is an ink comprising at least one pigment.

4. The method of claim 2 wherein the colorant is an ink comprising at least one dye.

5. The method of claim 2 wherein the colorant is an organic-based ink.

6. The method of claim 2 wherein the colorant is an ink having a viscosity of from about 1 to about 50 centipoise.

7. The method of claim 2 wherein the ink has a viscosity of from about 2 to about 30 centipoise.

8. The method of claim 2 comprising dispersing a first colorant into the contact lens before printing.

9. The method of claim 2 further comprising coating the lens with a binding solution.

10. The method of claim 9 wherein the coating is done during printing.

11. The method of claim 9 wherein the coating is done after printing.

12. The method of claim 9 wherein the binding solution comprises at least one monomer.

13. The method of claim 9 wherein the binding solution comprises at least one hydrophilic monomer and at least one hydrophobic monomer.

14. The method of claim 13 wherein the binding solution comprises 2-hydroxyethyl methacrylate and 2-ethoxyethyl methacrylate.

15. The method of claim 12 wherein the binding solution further comprises an adhesion promoter.

16. A colored contact lens produced by the process of claim 1.

17. The method of claim 1 wherein the printing process is electrophotographic printing

18. The method of claim 17 wherein a electrophotographic printer prints the colorant in the form of toner directly onto the contact lens using a photosensitive sphere.

19. The method of claim 18 wherein the sphere rolls across the contact lens to transfer toner to the lens.

20. The method of claim 18 wherein the lens is placed on the sphere and toner is transferred to the lens using a toner transfer mechanism.

21. The method of claim 20 wherein the toner transfer mechanism is selected from the group consisting of a roller, a mold, and a ball.

22. The method of claim 17 wherein a electrophotographic printer prints the colorant in the form of toner directly onto the contact lens using a photosensitive hemisphere.

23. The method of claim 18 wherein the hemisphere contacts the contact lens to transfer toner to the lens.

24. The method of claim 18 wherein the lens is placed on the hemisphere and toner is transferred to the lens using a toner transfer mechanism.

25. The method of claim 20 wherein the toner transfer mechanism is selected from the group consisting of a roller, a mold, and a ball.

26. The method of claim 1 wherein the printing process is thermal transfer.

27. The method of claim 26 using a multiple-color complement system

28. The method of claim 27 wherein each component color of the multiple-color complement system is associated with a ribbon for transferring the component color to the contact lens or to a film on a mold for the contact lens.

29. The method of claim 28 wherein each ribbon is flat.

30. The method of claim 28 wherein each ribbon is curved.

31. The method of claim 1 wherein the printing process is photographic development.

32. The method of claim 31 wherein a photographic development system is used, the system comprising:

a) a film composed of a plurality of light sensitive layers;

b) a computer-controlled source to expose each of the plurality of light sensitive layers; and

c) a chemical processing system to develop each of the exposed light sensitive layers, thereby forming a plurality of colors onto the contact lens or onto a film in a mold for the contact lens.

33. A method of making a colored contact lens, the method comprising:

(a) printing a first layer of a colorant in a first pattern onto a contact lens using a printing process selected from the

group consisting of ink jet printing, electrophotographic printing, thermal transfer, and photographic development;

(b) printing at least one second layer of a colorant in a second pattern onto a contact lens using a printing process selected from the group consisting of ink jet printing, electrophotographic printing, thermal transfer, and photographic development; and

(c) coating the colored contact lens with a binding solution comprising a monomer.

34. A colored contact lens produced by the process of claim 33.

35. The method of claim 33 wherein step (c) is performed simultaneously with steps (a) and (b).

36. The method of claim 33 wherein the second pattern overlaps the first pattern, at least in part.

37. The method of claim 33 wherein the second pattern overlaps the first pattern such that at least 50% if the first pattern is covered.

38. The method of claim 33 wherein the coating is applied to the contact lens only in regions that are not in an optical zone.

39. An improved method of making colored contact lenses, the improvement comprising printing at least one layer of a colorant onto a contact lens using a printing process selected from the group consisting of ink jet printing, electrophotographic printing, thermal transfer, and photographic development.

40. The improved method of claim 39 wherein the printing step comprises printing onto a film in a mold wherein the film becomes integral with the contact lens when the contact lens is formed in the mold.

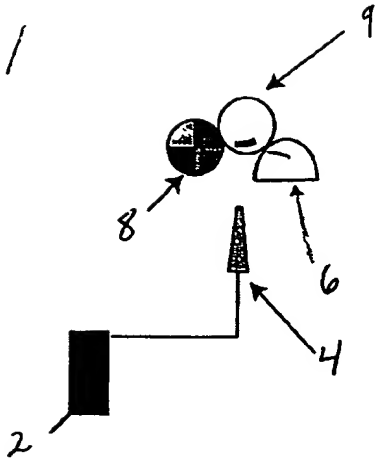
41. The improved method of claim 39 wherein the printing step comprises printing directly onto the contact lens.

42. The improved method of claim 39 wherein the printing step comprises printing onto a pad such that the pad prints directly onto the contact lens.

ABSTRACT OF THE DISCLOSURE

A method of making a colored contact lens comprises printing at least one layer of a colorant onto a contact lens using a printing process selected from the group consisting of ink jet printing, electrophotographic printing, thermal transfer, and photographic development. Printing can be done directly on the contact lens, on a film in a mold where the contact lens is formed, or on a cliché pad. Multiple layers of colorants can be printed onto a contact lens.

Figure 1



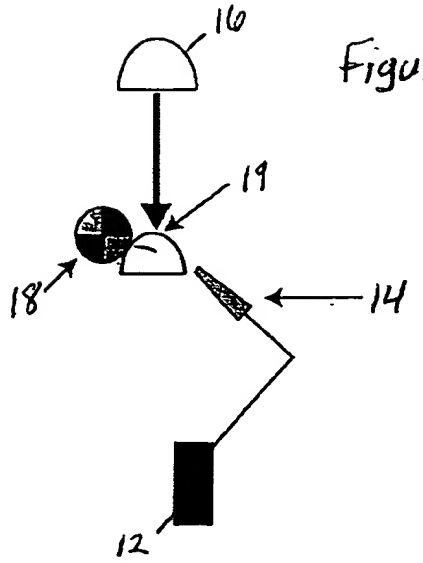


Figure 2

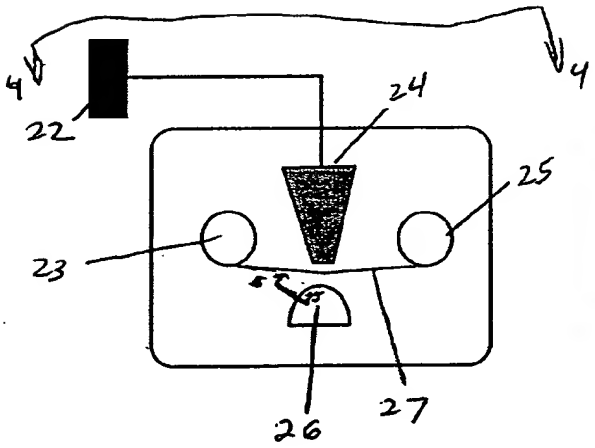


Figure 3

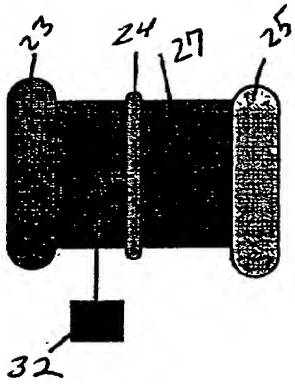


Figure 4

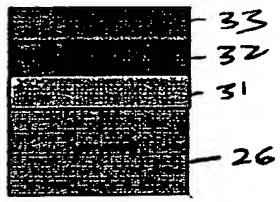


Figure 5

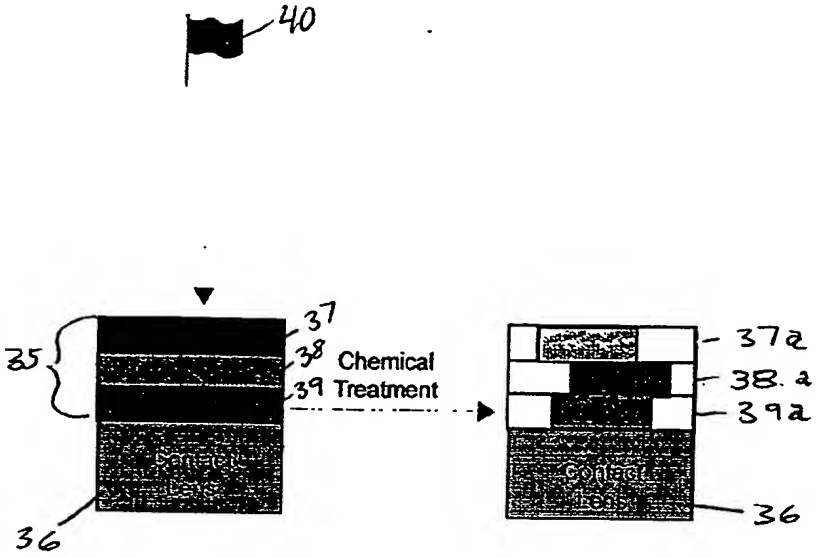


Figure 6

Figure 7